



DR. CHRISTA BURGER
S-IMS-U1/BGH

Wacker Chemie AG
Johannes-Hess-Strasse 24
84489 Burghausen, Germany
Tel. +49 8677 83 5937
Fax +49 8677 83 3043
christa.burger@wacker.com

Statement on Biocompatibility

The products **WACKER ELASTOSIL® R Plus 4001/50-60 MH** have neither been tested according to USP Class VI nor to ISO 10993. These tests have only been carried out with **ELASTOSIL® R 4001/40 MH** (now renamed **R Plus 4001/40 MH**) which is that product of the **R Plus 4001** series having the lowest content of filler and which therefore can be considered as the worst case material referring to possible migration of hazardous compounds. **ELASTOSIL® R Plus 4001/40 MH** passed the USP Class VI (acute systemic and intracutaneous toxicity, implantation) and ISO 10993 tests on cytotoxicity, skin irritation and sensitization tests without showing any adverse effects. We therefore firmly believe that the test results received with **ELASTOSIL® R 4001/40 MH** (renamed **R Plus 4001/40 MH**) are representative also for the higher duro grades, **ELASTOSIL® R Plus 4001/50 – 60 MH**.

This statement does not imply that the finished product manufactured from those ingredients is considered safe by regulatory bodies. Responsibility for compliance of the finished article with existing legislation resides with the person(s) producing and placing the article on the market.

Wacker-Chemie AG

Burghausen, May 22, 2013

Dr. C. Burger
GB-S-IMS Manager Product Stewardship 1

This information is considered accurate and reliable as of the date appearing above and is presented in good faith. It is valid from the date of issue unless legal changes become effective. Because use conditions and applicable laws may differ from one location to another and may change with time, Recipient is responsible for determining whether the information in this document is appropriate for recipient's use. Since Wacker has no control over how this information may be ultimately used, all liability is expressly disclaimed and Wacker assumes no obligation or liability therefore. No warranty, express or implied, is given nor is freedom from any patent owned by Wacker or others to be inferred.